

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MISSOURI  
WESTERN DIVISION**

**ANGELINA FLORES and  
HOLLY GROSSENBACHER,  
Individually, and on behalf of all others  
similarly situated,**

**Plaintiffs,**

**v.**

**CROWN LABORATORIES, INC.,**

**Defendant.**

**Case No.**

**JURY TRIAL REQUESTED**

**CLASS ACTION COMPLAINT**

Angela Flores and Holly Grossenbacher (collectively “Plaintiffs”), individually, and on behalf of all others similarly situated, by and through their attorneys, bring this class action complaint against Defendant Crown Laboratories, Inc. (“Defendant”). Plaintiffs allege the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiffs further believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**NATURE OF THE ACTION**

1. This is a class action lawsuit regarding Defendant’s manufacturing, distribution, advertising, marketing, and sale of PanOxyl® branded benzoyl peroxide products<sup>1</sup> (the “BPO Products”) that contain dangerously high levels of benzene, a carcinogen that has been linked to leukemia and other blood cancers.

2. Throughout this Complaint, references to federal law and Food and Drug Administration (“FDA”) regulations are merely to provide context and are not intended to raise a

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<sup>1</sup> The BPO Products refer to PanOxyl® Acne Creamy Wash 4% BPO and PanOxyl® Acne Foaming Wash 10% BPO.

federal question of law. All claims alleged herein arise out of violations of Missouri and Louisiana law, which in no way conflict, interfere with, or impose obligations that are materially different than those imposed by federal law.

3. Prior to placing the BPO Products into the stream of commerce and into the hands of consumers to use on their skin, Defendant knew or should have known that the BPO Products contained benzene, but misrepresented, omitted, and concealed this fact to consumers, including Plaintiffs and Class members, by not including benzene on the BPO Products' labels or otherwise warning consumers about its presence.

4. Plaintiffs and Class members reasonably relied on Defendant's representations that the BPO Products were safe, unadulterated, and free of any carcinogens that are not listed on the label.

5. Plaintiffs and Class members purchased the BPO Products, which contain harmful levels of benzene.

6. The BPO Products are worthless because they contain benzene at levels which render the BPO Products adulterated, misbranded, and illegal to sell under federal and Missouri and Louisiana law.

7. Defendant is therefore liable to Plaintiffs and Class members for misrepresenting and/or failing to disclose or warn that the BPO Products contain benzene or that the Products degrade into benzene.

## **PARTIES**

8. Plaintiff Angelina Flores is a resident and citizen of Raytown, Missouri, located in Jackson County. Plaintiff purchased Defendant's PanOxyl® Acne Foaming Wash 10% BPO on or about July 2023 at Walmart in Jackson County, Missouri. When purchasing the BPO Products, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the BPO Products were properly manufactured, free from defects, safe for their intended use, and not adulterated or misbranded.

Plaintiff relied on these representations and warranties in deciding to purchase the BPO Products manufactured by Defendant, and these representations and warranties were part of the basis of the bargain. Had Plaintiff known that benzene was contained in the Products at the time of purchase or that the Products degraded to form benzene, Plaintiff would not have purchased and used the Products at all or would have paid significantly less for them. Plaintiff would have never paid a premium for BPO Products that contain the carcinogen benzene.

9. Plaintiff Holly Grossenbacher is a resident and citizen of Chalmette, Louisiana, located in St. Bernard Parish. Plaintiff purchased Defendant's PanOxyl® Acne Foaming Wash 10% BPO online from Walmart on or about 2023. When purchasing the BPO Products, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the BPO Products were properly manufactured, free from defects, safe for their intended use, and not adulterated or misbranded. Plaintiff relied on these representations and warranties in deciding to purchase the BPO Products manufactured by Defendant, and these representations and warranties were part of the basis of the bargain. Had Plaintiff known that benzene was contained in the Products at the time of purchase or that the Products degraded to form benzene, Plaintiff would not have purchased and used the Products at all or would have paid significantly less for them. Plaintiff would have never paid a premium for BPO Products that contain the carcinogen benzene.

10. Standing is satisfied by alleging economic injury. Here, Plaintiffs suffered economic injury when they spent money to purchase BPO Products they would not otherwise have purchased, or paid less for, absent Defendant's misconduct, as alleged herein. Members of the putative class have likewise suffered economic injuries in that they have spent money to purchase BPO Products they would not otherwise have purchased, or paid less for, absent Defendant's

misconduct, as alleged herein.

11. Defendant Crown Laboratories, Inc. is a Delaware York corporation with its principal place of business at 207 Mockingbird Land, Johnson City, Tennessee 37604. Crown markets, distributes, and sells various skin care products, including PanOxyl® Acne Creamy Wash 4% BPO and PanOxyl® Acne Foaming Wash 10% BPO.

12. Defendant markets, sells, and distributes the BPO Products in Missouri and Louisiana, and throughout the United States. The BPO Products, including those purchased by Plaintiffs and Class members, are available for sale on Defendant's website ([www.panoxyl.com](http://www.panoxyl.com)), on third party websites (e.g. [www.amazon.com](http://www.amazon.com)), and are sold by various retailers, including Walmart, Walgreens, Target, and Ulta Beauty, both online and in their brick-and-mortar stores throughout the United States. Defendant authorized the false, misleading, and deceptive marketing, advertising, distribution, and sale of its BPO Products.

### **JURISDICTION AND VENUE**

13. This Court has original jurisdiction over all causes of action asserted herein under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because the matter in controversy exceeds the sum or value of \$5,000,000 exclusive of interest and costs and is a class action in which there are more than 100 class members and many members of the class are citizens of a state different than Defendant.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Plaintiffs suffered injury as a result of Defendant's acts in this district, many of the acts and transactions giving rise to this action occurred in this district, Defendant conducts substantial business in this district, Defendant has intentionally availed themselves of the laws and markets of this district, and Defendant is subject to personal jurisdiction in this district.

### **FACTUAL ALLEGATIONS**

## **I. Defendant's History in the Industry**

15. Defendant Wal-Mart Stores, Inc. manufactures, markets, distributes, and sells various skin care products, including PanOxyl® Acne Creamy Wash 4% BPO and PanOxyl® Acne Foaming Wash 10% BPO.

16. Benzoyl peroxide is an active ingredient in all the BPO Products.

17. All of Defendant's BPO Products are manufactured in the same manner.

18. All lots of Defendant's BPO Products systematically degrade to form benzene. As noted below, this is supported by testing of 66 acne treatment products containing benzoyl peroxide, all of which tested positive for benzene at various levels ranging from 2,000 ppm to 1.8 ppm. Defendant's PanOxyl® Acne Foaming Wash 10% BPO, in particular, was tested and found to contain over 170 ppm benzene. These results have been published in peer-reviewed literature.<sup>2</sup>

19. The rates of degradation and benzene impurities in the BPO Products occur at a systematic rate.

## **II. Evidence of Benzene's Danger**

20. Benzene is used primarily as a solvent in the chemical and pharmaceutical industries, as a starting material and intermediate in the synthesis of numerous chemicals, and in gasoline. The major United States source of benzene is petroleum. The health hazards of benzene have been recognized for over one hundred years.

21. "Human exposure to benzene has been associated with a range of acute and long-term adverse health effects and diseases, including cancer and haematological effects."<sup>3</sup>

22. A toxicity assessment by the Centers for Disease Control and Prevention has shown benzene can harm the central nervous system and may affect reproductive organs.<sup>4</sup>

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<sup>2</sup> Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID: PMC10939128.

<sup>3</sup> <https://www.who.int/publications/i/item/WHO-CED-PHE-EPE-19.4.2>.

<sup>4</sup> <https://www.atsdr.cdc.gov/toxprofiles/tp3.pdf>.

23. According to the World Health Organization, “Benzene is a genotoxic carcinogen in humans and no safe level of exposure can be recommended.”<sup>5</sup>

24. According to the National Cancer Institute, “[e]xposure to benzene increases the risk of developing leukemia and other blood disorders.”<sup>6</sup>

25. According to the National Toxicology Program, benzene is “known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans.”<sup>7</sup>

26. Benzene has also been “found to be carcinogenic to humans” by the International Agency for Research on Cancer (“IARC”). Benzene was “[f]irst evaluated by IARC in 1974 . . . and was found to be carcinogenic to humans (Group 1), a finding that has stood since that time.”<sup>8</sup>

As noted by the IARC:

In the current evaluation, the Working Group again confirmed the carcinogenicity of benzene based on *sufficient evidence* of carcinogenicity in humans, *sufficient evidence* of carcinogenicity in experimental animals, and *strong* mechanistic evidence. . . . The Working Group affirmed the strong evidence that benzene is genotoxic, and found that it also exhibits many other key characteristics of carcinogens, including in exposed humans. In particular, benzene is metabolically activated to electrophilic metabolites; induces oxidative stress and associated oxidative damage to DNA; is genotoxic; alters DNA repair or causes genomic instability; is immunosuppressive; alters cell proliferation, cell death, or nutrient supply; and modulates receptor-mediated effects.<sup>9</sup>

27. The U.S. Food and Drug Administration (“FDA”) also recognizes that “[b]enzene is a carcinogen that can cause cancer in humans”<sup>10</sup> and classifies benzene as a “Class 1” solvent that should be “avoided” in drug manufacturing.<sup>11</sup> FDA guidance provides: “Solvents in Class 1 [e.g. benzene] should not be employed in the manufacture of drug substances, excipients, and drug

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<sup>5</sup> WHO Guidelines for Indoor Air Quality: Selected Pollutants (2010).

<sup>6</sup> <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene>.

<sup>7</sup> <http://ntp.niehs.nih.gov/go/roc/content/profiles/benzene.pdf> (emphasis in original).

<sup>8</sup> Benzene / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017: Lyon, France), at p. 33.

<sup>9</sup> *Id.* at 34.

<sup>10</sup> [https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1\\_](https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1_)

<sup>11</sup> [https://www.fda.gov/media/71737/download\\_](https://www.fda.gov/media/71737/download_)

products because of [its] unacceptable toxicity.”<sup>12</sup>

28. In July 2021, the FDA conducted a “Health Hazard Evaluation” on “Multiple Aerosol Sunscreen Products” manufactured by Johnson & Johnson.<sup>13</sup> The evaluation was requested following testing which showed benzene levels ranging “from 11.2 to 23.6 ppm” in Johnson & Johnson’s aerosol sunscreen products. Specifically, the agency requested “an evaluation of the likelihood and risks associated with using aerosol sunscreens that contain benzene 11.2 to 23.6 ppm,” which “levels exceed the guideline value provided by ICH [Q3C]<sup>14</sup> and USP<sup>15</sup>” limits, states the report. The evaluation concluded that serious adverse effects, including potential for “life-threatening” issues or “permanent impairment of a body function” were “likely to occur” at exposure levels within that range. In addition, the evaluation stated that “individuals with altered skin absorption (i.e., infants, elderly, broken skin) and individuals who are exposed to benzene from other sources . . . may be at greater risk.”

29. On December 27, 2023, in response to reports of benzene contamination in various drug products, the FDA issued an “Alert,” stating: “Drug manufacturers with a risk for benzene contamination should test their drugs accordingly and should not release any drug product batch that contains benzene above 2 ppm[.] ... If any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]”<sup>16</sup>

30. “Even in trace amounts, benzene is known to pose a health risk from exposure

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<sup>12</sup> *Id.*

<sup>13</sup> [https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA\\_Benzene\\_in\\_Sunscreen\\_Assessment](https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment).

<sup>14</sup> The term “ICH” refers to The International Conference on Harmonization (ICH) Q3C Impurities: Residual Solvents guidance (December 1997), at <https://www.fda.gov/media/71736/download?attachment>.

<sup>15</sup> The term “USP” refers to United States Pharmacopeia (USP) Residual Solvents, at [https://www.uspnf.com/sites/default/files/usp\\_pdf/EN/USPNF/generalChapter467Current.pdf](https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf).

<sup>16</sup> <https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs>.

routes that include inhalation, ingestion, dermal absorption, and skin or eye contact.”<sup>17</sup>

31. As with other topically applied products, such as sunscreen, the application of BPO Products specifically increases the absorption rate of benzene through the skin, thereby increasing the risk of harm.<sup>18</sup> Indeed, “[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation.”<sup>19</sup> Accordingly, The National Institute for Occupational Safety and Health (“NIOSH”) recommends protective equipment be worn by workers exposed or expecting to be exposed to benzene at concentrations of 0.1 ppm and defines “inhalation, skin absorption, ingestion, skin and/or eye contact” as exposure routes or paths.<sup>20</sup>

32. The Environmental Protection Agency (“EPA”) similarly recognizes the cancer risks of benzene, noting that “Benzene is classified as a ‘known’ human carcinogen (Category A) under the Risk Assessment Guidelines of 1986.”<sup>21</sup> “[B]enzene is characterized as a known human carcinogen for all routes of exposure based on convincing human evidence as well as supporting evidence from animal studies.”<sup>22</sup>

33. EPA has set 0.0005 ppm as the maximum permissible level of benzene in drinking water, with a stated goal of “zero.”<sup>23</sup>

34. In its review of non-cancer adverse health effects of benzene, the EPA cited epidemiologic evidence that “support a threshold of benzene hematotoxicity<sup>24</sup> in humans in the 5-

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<sup>17</sup> Hudspeth, A., et al., Independent Sun Care Product Screening for Benzene Contamination, Environmental Health Perspectives, 130:3, Online Publication 29 March 2022.

<sup>18</sup> *Valisure Detects Benzene in Sunscreen*, VALISURE BLOG (May 25, 2021), <https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/>.

<sup>19</sup> *Facts About Benzene*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://emergency.cdc.gov/agent/benzene/basics/facts.asp>.

<sup>20</sup> *NIOSH Pocket Guide to Chemical Hazards - Benzene*, THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), <https://www.cdc.gov/niosh/npg/npgd0049.html>.

<sup>21</sup> [https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance\\_nmbr=276](https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance_nmbr=276).

<sup>22</sup> *Id.*

<sup>23</sup> <https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations>.

<sup>24</sup> The term “hematotoxic” means “poisonous to the blood and to the organs and tissues involved in the production of blood, such as the bone marrow.” <https://clinicalinfo.hiv.gov/en/glossary/hematotoxic>.



19 ppm range[.]”<sup>25</sup> As noted in the EPA’s review, “[c]learly, if a significantly elevated risk of benzene poisoning is an indication of hematotoxicity, then certainly exposures to benzene at 5-19 ppm are hematotoxic.”<sup>26</sup>

### III. Discovery of Benzene in the BPO Products

35. On March 5, 2024, Valisure LLC (“Valisure”) submitted a public citizens petition to the FDA requesting a recall and suspension of sales of benzoyl peroxide from the U.S. market. The petition was based on Valisure’s findings that numerous BPO products contained elevated levels of benzene, a known human carcinogen.<sup>27</sup>

36. “Valisure operates an analytical laboratory that is accredited under International Organization for Standardization (‘ISO/IEC’) 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238),” and it “is registered with the Drug Enforcement Administration (License # RV0484814).”<sup>28</sup> As an industry leader in independent chemical testing of medications, Valisure works with large private health care systems like Kaiser Permanente and governmental healthcare systems like the Military Health System through the U.S. Department of Defense.<sup>29</sup>

37. In its citizens petition, Valisure reported its testing results for benzene in various types of BPO drug products, mostly utilizing gas chromatography and detection by mass spectrometry (“GC-MS”) instrumentation that allows mass spectral separation and utilizing selected ion chromatograms, along with Selected Ion Flow Tube-Mass Spectrometry (“SIFT-MS”) for detection of benzene released into the air around certain BPO products. Valisure also used

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<sup>25</sup> EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38. [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0276tr.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf).

<sup>26</sup> *Id.*

<sup>27</sup> [https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b\\_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf](https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf).

<sup>28</sup> *Id.*

<sup>29</sup> Valisure Signs Agreement with Department of Defense to Independently Test & Quality Score Drugs. (August 8, 2023). PR Newswire. (<https://www.prnewswire.com/newsreleases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs301895301.html>).

other orthogonal approaches for confirmation of a few select products.<sup>30</sup>

38. GC-MS “is generally considered one of the most accurate analyses available.”<sup>31</sup> Indeed, the FDA used the same method to test for impurities like benzene in hand sanitizers.<sup>32</sup>

39. “The GC-MS method described in [Valisure’s] petition utilized body temperature (37°C) for oven incubation. 40°C has been previously used for benzene analysis from liquid pharmaceuticals and beverages, and reduced false positive results compared with higher-temperature incubation.”<sup>33</sup>

40. As reported, Valisure analyzed 66 different BPO containing drug products, both prescription and over-the-counter (“OTC”) for the presence of benzene. Valisure acquired the products and incubated the products at 50°C<sup>34</sup> for 18 days, with samples measured at day 0, 4, 10, 14, and 18. These BPO containing products represented creams, lotions, gels, washes, liquids, and bars, and included analysis of Defendant’s Equate® Beauty Acne Wash 10% BPO cream.<sup>35</sup> As demonstrated below, results from this 50°C stability showed that every one of the 66 products, including Defendant’s Equate® Beauty Acne Wash 10% BPO cream, contained some level of benzene ranging from a maximum of 2,000 ppm to 1.8 ppm.<sup>36</sup>

41. Valisure’s findings with respect to its benzene testing of the BPO Product has been published in peer-reviewed literature.<sup>37</sup>

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<sup>30</sup> *Id.* at 10.

<sup>31</sup> *GC/MS Analysis*, Element, <https://www.element.com/materials-testing-services/chemical-analysis-labs/gcms-analysis-laboratories>.

<sup>32</sup> *Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection of Listed Impurities in Hand Sanitizers*, FDA (Aug. 24, 2020), <https://www.fda.gov/media/141501/download>.

<sup>33</sup> *Valisure Citizen Petition* at 10-11 (citations omitted).

<sup>34</sup> “50°C (122°F) is not only a reasonable temperature that ‘the product may be exposed to during distribution and handling by consumers’ but is an accepted incubation temperature used by the pharmaceutical industry for performing accelerated stability studies with a duration of at least 3 months.” *Id.* at 18-19 (citations omitted).

<sup>35</sup> *Id.* at 16, 23.

<sup>36</sup> *Id.* at 16-18.

<sup>37</sup> Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. *Environ Health Perspect.* 2024

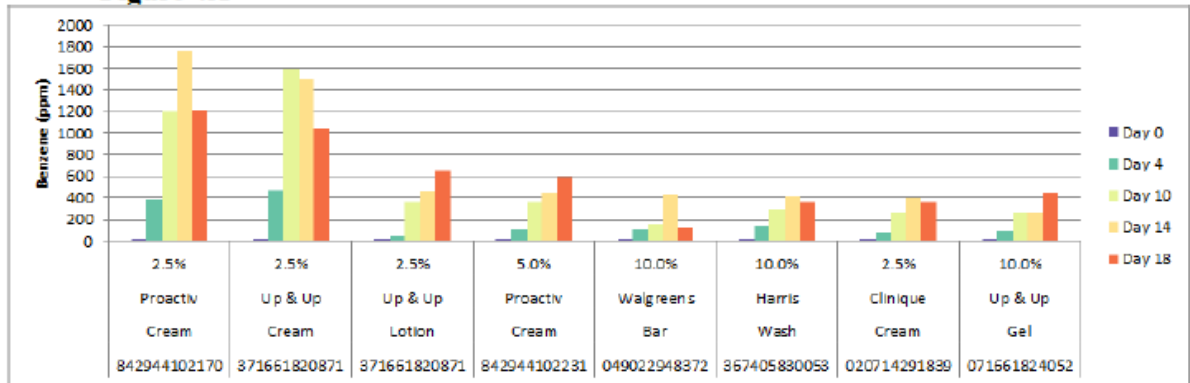
42. As noted in the chart below, testing conducted on Defendant's PanOxyl® Acne Foaming Wash 10% BPO in particular revealed benzene levels over 170 ppm.<sup>38</sup>

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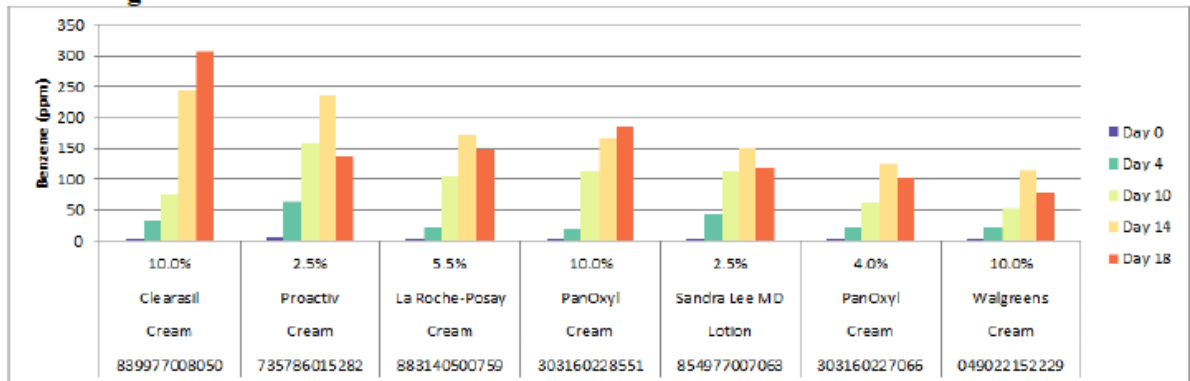
Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID: PMC10939128.

<sup>38</sup> *Valisure Citizen Petition* at 16. The Universal Product Code ("UPC") for the test conducted on PanOxyl® Acne Foaming Wash 10% BPO is identified as 303160228551.

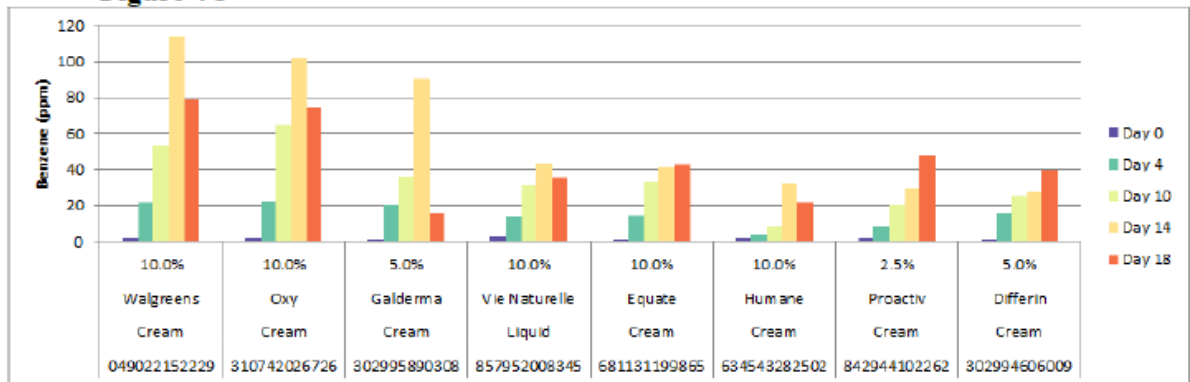
**Figure 4A**



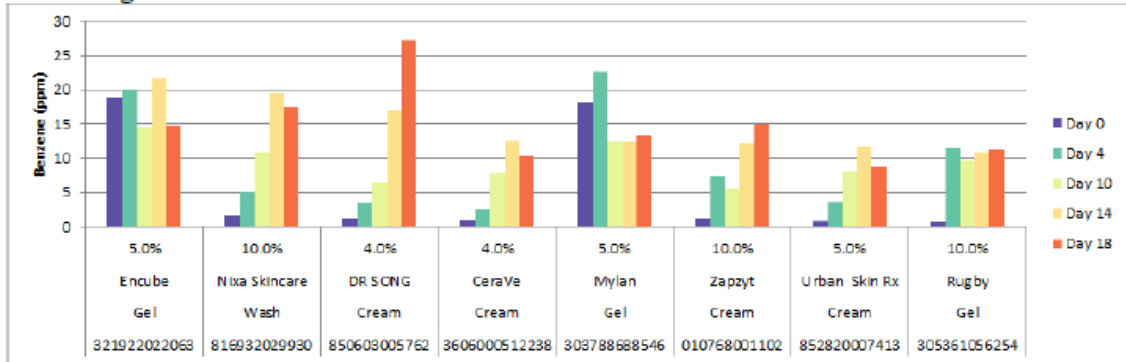
**Figure 4B**



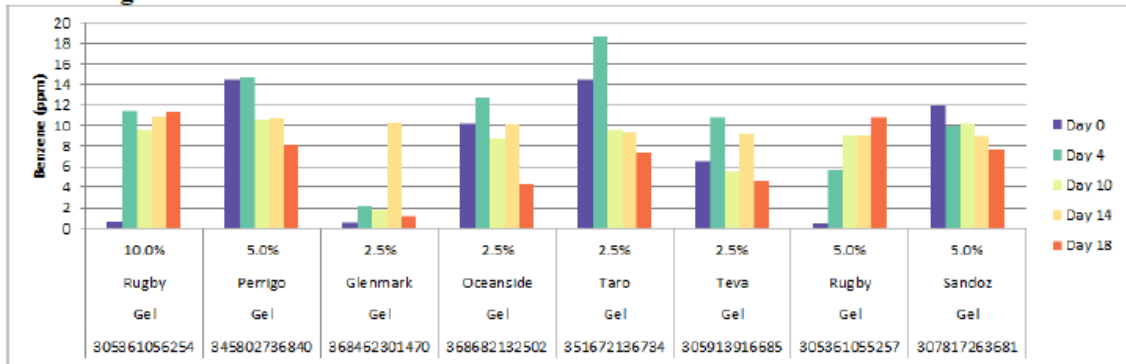
**Figure 4C**



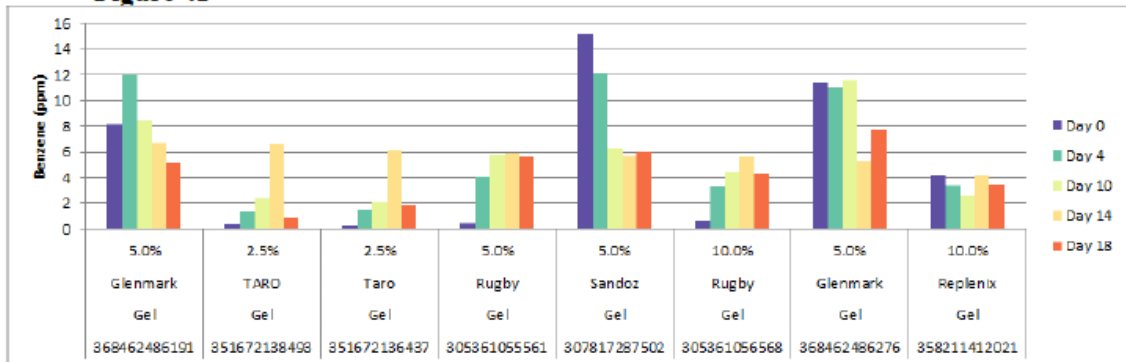
**Figure 4D**



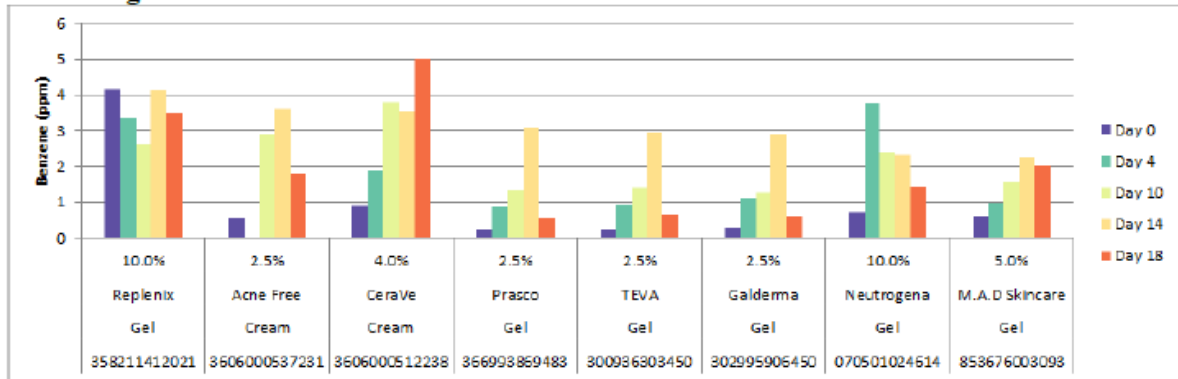
**Figure 4E**



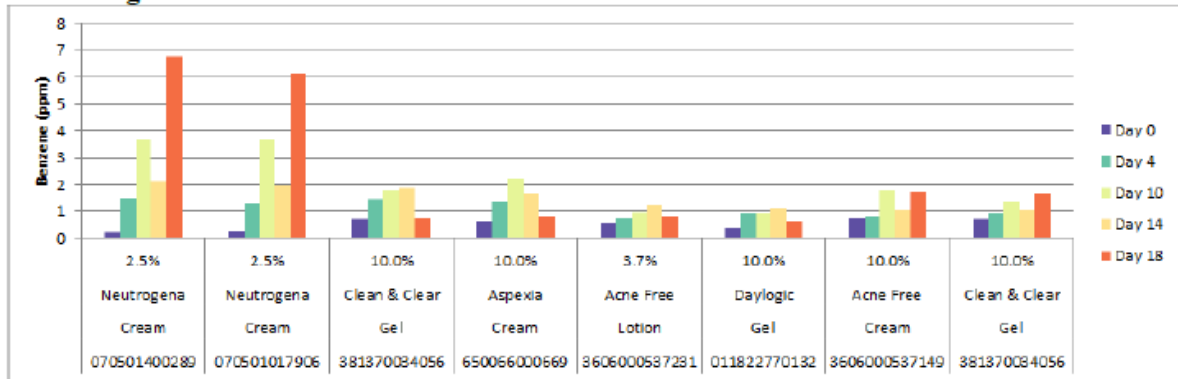
**Figure 4F**



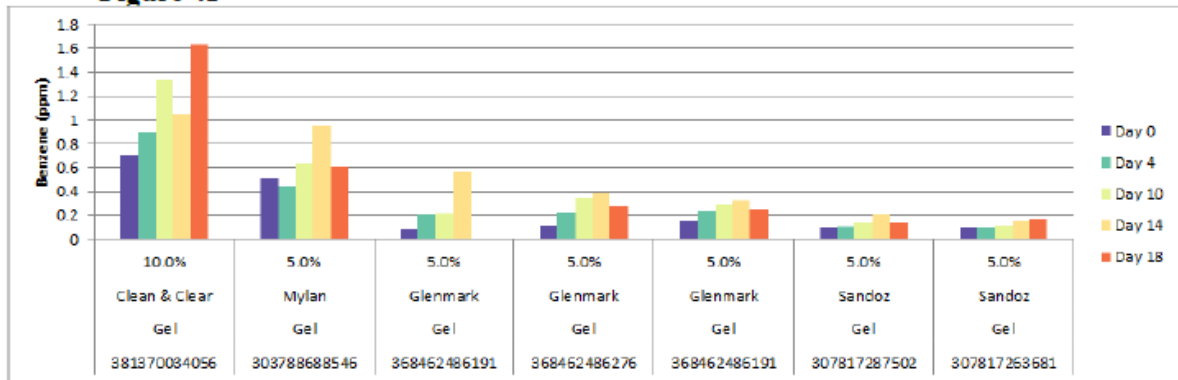
**Figure 4G**



**Figure 4H**



**Figure 4I**



43. The BPO Products are not designed to contain benzene, and no amount of benzene is acceptable in acne treatment products such as the BPO Products manufactured, distributed, and sold by Defendant. Further, although Defendant lists the ingredients on the BPO Products' labels, Defendant fails to disclose on the Products' labeling or anywhere in its marketing that the BPO Products contain benzene or that the Products can degrade to form benzene.

44. Despite its knowledge that the BPO Products contain benzene, Defendant has failed to issue a voluntary recall of the BPO Products.

#### **IV. Benzene Renders the BPO Product Adulterated, Misbranded, and Illegal to Sell**

45. The BPO Products are “drugs” used to treat acne (i.e., *acne vulgaris*), formulated with a chemical called benzoyl peroxide, along with other inactive ingredients, to make acne treatment creams, washes, scrubs, and bars. Before being sold to the public, the BPO Products must be made in conformity with current good manufacturing practices and must conform to quality, safety, and purity specifications. Under the FDCA, a drug is adulterated “if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice...”<sup>39</sup>

46. Benzene is restricted by the FDA to 2 ppm where its use in manufacturing “is unavoidable in order to produce a drug product with a significant therapeutic advance.”<sup>40</sup> Except in such “limited cases,” Class 1 solvents such as benzene should not be employed in the

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<sup>39</sup> 21 U.S.C. § 351(a)(2)(B).

<sup>40</sup> 2018 ICH Q3C guidance, at p. 5. US FDA, June 2017 (available at <https://www.fda.gov/media/71737/download>).

manufacture of drug substances or drug products “because of their unacceptable toxicity.”<sup>41</sup> Defendant’s BPO Products do not meet this safe harbor exception. This is because the use of benzene in the manufacture of the BPO Products is not “unavoidable,” nor does the use of benzene in BPO Products provide a “significant therapeutic advance.” That is why, in December 2022, the FDA issued a statement alerting manufacturers to the risk of benzene contamination and warned that any drug product containing more than 2 ppm benzene was adulterated and should be recalled. This statement was updated on December 27, 2023, and still provides that drug manufacturers “should not release any drug product batch that contains benzene above 2 ppm” and “[i]f any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]”<sup>42</sup>

47. It is therefore illegal under federal law to manufacture and distribute drug products in the United States that contain benzene above 2 ppm.<sup>43</sup> Hence, within the past three years alone, the FDA has announced over a dozen recalls of various drug and cosmetic products identified as containing “low levels” or even “trace levels” of benzene, including certain hand sanitizers and aerosol drug products like sunscreens and antiperspirants.<sup>44</sup>

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<sup>41</sup> *Reformulating Drug Products That Contain Carbomers Manufactured With Benzene*; Guidance for Industry – Final Guidance. US FDA, December 27, 2023 (citing 2018 ICH Q3C guidance at p. 5) (available at <https://www.regulations.gov/document/FDA-2023-D-5408-0002>).

<sup>42</sup> <https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs>. The FDA cannot force a drug manufacturer to recall a contaminated or adulterated drug. <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp> (“While FDA cannot force a company to recall a drug, companies usually will recall voluntarily or at FDA’s request”).

<sup>43</sup> 21 U.S.C. § 351(a)(2)(B).

<sup>44</sup> <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogena-and-aveeno-aerosol>; <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due-0>; <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pg-issues-voluntary-recall-specific-old-spice-and-secret-aerosol-spray-antiperspirants-and-old->



48. It is also illegal to distribute benzene contaminated drug products under Missouri and Louisiana law. For example, in Missouri, “[a] drug ... shall be deemed to be adulterated: (1) If it consists in whole or part of any filthy, putrid, or decomposed substance; or (2) It has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or ... (6) If [its] purity or quality falls below [] that which it purports or is represented to possess.”<sup>45</sup>

49. Because all of Defendant’s BPO Products contain benzene above 2 ppm, the Products (1) consist of a filthy, putrid, and/or decomposed substance (i.e. benzene), (2) have been produced under conditions whereby it is injurious to health (i.e. benzene exposure), (3) have a purity or quality that falls below that which it purports or is represented to possess. As a result, it is illegal under Missouri law for Defendant to distribute any of its BPO Products in the State of Missouri.

50. As alleged herein, Defendant’s BPO Products contain more than 2 ppm benzene and have been distributed to residents of the State of Missouri and Louisiana, including Plaintiffs, in violation of Missouri and Louisiana law.

51. The manufacture of any misbranded or adulterated drug is prohibited under federal law<sup>46</sup> and Missouri<sup>47</sup> and Louisiana<sup>48</sup> state law.

52. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.<sup>49</sup>

53. The receipt in interstate commerce of any adulterated or misbranded drug is also

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spice#:~:text=The%20Procter%20%26%20Gamble%20Company%20(NYSE,level%20due%20to%20the%20presence.

<sup>45</sup> Mo. Rev. Stat. § 196.095 (1), (2), (6).

<sup>46</sup> 21 U.S.C. §331(g).

<sup>47</sup> Mo. Rev. Stat. § 196.015(1) (“The following acts and the causing thereof within the state of Missouri are hereby prohibited: (1) The manufacture, sale, or delivery, holding or offering for sale any ... drug ... that is adulterated or misbranded”).

<sup>48</sup> LSA-R.S. 40:636 (“The following acts and the causing thereof are prohibited: ... (2) the adulteration, or misbranding, of any food, drug, device or cosmetic in commerce”).

<sup>49</sup> Mo. Rev. Stat. § 196.015(1); LSA-R.S. 40:636(1).

unlawful.<sup>50</sup>

54. Among the ways a drug may be adulterated are:

If it consists in whole or in part of any filthy, putrid, or decomposed substance; or . . . whereby it may have been rendered injurious to health; . . .<sup>51</sup>

55. Among the ways a drug may be misbranded include:

- (1) The dissemination of any false advertisement.<sup>52</sup>
- (2) The using, on the labeling of any drug or in any advertising related to such drug, of any representation or suggestion that . . . such drug complies with the provisions of such section.<sup>53</sup>

56. Defendant could have avoided any potential for benzene contamination in the BPO Products by changing the manufacturing process or raw ingredients, and the BPO Products could have been sold with absolutely no benzene in them. Specifically, BPO as a raw material is known to be thermally stable at purities as high as 75% up to temperatures of 98°C.<sup>54</sup> Valisure also evaluated pure BPO reference powder in its GC-MS analytical system and found no evidence of the instability and formation of benzene seen in formulated final products of BPO containing acne treatments.<sup>55</sup> Thus, if BPO is inherently stable as a pure, crystalline powder, a reformulated product that focuses on substantially reducing or entirely preventing the degradation of BPO into benzene could potentially be developed.<sup>56</sup>

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<sup>50</sup> Mo. Rev. Stat. § 196.015(3); LSA-R.S. 40:636(3).

<sup>51</sup> 21 U.S.C. §351(a)(2)(B). *See also* Mo. Rev. Stat. § 196.095(1) (“A drug or device shall be deemed to be adulterated: (1) If it consists in whole or part of any filthy, putrid, or decomposed substance”); LSA-R.S. 40:616 (“A drug is considered adulterated if it has been found to be such by any department of the United States Government, or: (1) If it consists in whole or in part of any filthy, putrid or decomposed substance. (2) If it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health”).

<sup>52</sup> Mo. Rev. Stat. § 196.015(5); *see also* LSA-R.S. 40:617(1), (2) (product is misbranded if its labeling is false or misleading in any particular).

<sup>53</sup> Mo. Rev. Stat. § 196.015(11); *see also* LSA-R.S. 40:617(1), (2) (product is misbranded if it is dangerous to health under conditions of the use prescribed in the labeling or advertising).

<sup>54</sup> *Valisure Citizens Petition* at 25 (citation omitted).

<sup>55</sup> *Id.*

<sup>56</sup> *See id.* at 25-26.

57. The mere presence of benzene in the BPO Products renders the Products adulterated, misbranded, and illegal to sell. As such, the BPO Products have no economic value and are worthless. Worse, as manufactured, the levels of benzene contained in the BPO Products—ranging from 5 ppm to over 12 ppm—"render [it] injurious to health" under the conditions of use prescribed in the labeling and advertising.<sup>57</sup>

58. As the FDA's July 2021 Health Hazard Evaluation concluded, serious adverse effects, including potential for "life-threatening" issues or "permanent impairment of a body function" were "likely to occur" at exposure levels of between 11.2 to 23.6 ppm benzene.<sup>58</sup>

59. Similarly, in its review of the noncancer effects of benzene, the EPA cites to studies in the medical literature which "support a threshold of benzene hematotoxicity in humans in the 5-19 ppm range, in broad agreement with the emerging exposure-response range that is apparent from the epidemiologic studies[.]"<sup>59</sup>

60. Defendant engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its misrepresentations and omissions regarding benzene in its BPO Products.

61. If Defendant had disclosed to Plaintiffs and putative Class members that the BPO Products contained or would degrade into benzene, Plaintiffs and putative Class members would not have purchased the BPO Products.

62. As manufacturers, distributors, and sellers of acne treatment products, Defendant had and have a duty to ensure that their BPO Products did not and do not contain excessive (or any) level of benzene, including through regular testing, especially before injecting the BPO Products into the stream of commerce for consumers to use on their skin.<sup>60</sup> This includes testing

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<sup>57</sup> Mo. Rev. Stat. § 196.095(2).

<sup>58</sup> [https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA\\_Benzene\\_in\\_Sunscreen\\_Assessment](https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment).

<sup>59</sup> EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38. [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0276tr.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf).

<sup>60</sup> 21 CFR 211.84; 21 CFR 211.160.

of raw materials and finished product batches prior to release to ensure they meet appropriate specifications for identity, strength, quality, and purity.<sup>61</sup> But Defendant made no reasonable effort to test its BPO Products for the presence of benzene or test whether the Products could degrade into benzene over the course of the shelf-life of the Products. Nor did it disclose to Plaintiffs in any advertising or marketing that its BPO Products contained or would degrade into benzene. To the contrary, Defendant represented the BPO Products were of merchantable quality, safe to use as prescribed, complied with federal and state law, and did not contain carcinogens or other impurities such as benzene.

#### **V. Defendant's Knowledge, Misrepresentations, Omissions, and Concealment of Material Facts Deceived Plaintiffs and Reasonable Consumers**

63. It is well known that BPO degrades to benzene when exposed to heat over time. This process was first reported in scientific literature as early as 1936.<sup>62</sup>

64. The issue of BPO decomposition into benzene has been previously identified and acted upon in industries other than in the acne treatment product industry.

65. For example, at least one patent application was filed by the chemical company Akzo Nobel N.V. in 1997 which “relates to a method for reducing the rate of free benzene and/or benzene derivative formation in BPO formulations based on organic plasticizers, such as pastes, emulsions, suspensions, dispersions and the like.”<sup>63</sup>

66. In the polymer manufacturing industry, BPO's decomposition into benzene has been studied and concern was raised specifically regarding the carcinogenic implications of the presence of benzene. In 1994, a paper was published<sup>64</sup> by researchers at Denmark's Department

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<sup>61</sup> 21 CFR 211.165.

<sup>62</sup> H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden*, HELV. CHIM. ACTA, 19, 338 (1936), <https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153>.

<sup>63</sup> Borys F. SchafranBryce Milleville (1997). “Reduction of benzene formation in dibenzoyl peroxide formulations.” Akzo Nobel N.V. Worldwide application, WO1997032845A1. (<https://patents.google.com/patent/WO1997032845A1/en>)

<sup>64</sup> Rastogi SC. Formation of benzene by hardeners containing benzoyl peroxide and phthalates. *Bull Environ Contam Toxicol*. 1994 Nov;53(5):747-52. doi: 10.1007/BF00196949. PMID: 7833612.

of Environmental Chemistry titled “Formation of benzene by hardeners containing benzoyl peroxide and phthalates” and stated:

Recently, during the investigation of benzene residues in chemical products (Rastogi 1993a),<sup>65</sup> it was observed that the benzene content in benzoyl peroxide containing hardeners of two component repair-sets (fillers, elastomers) were >2 % (w/w) [20,000 ppm]. Benzene is carcinogenic (IARC 1982), and its use in consumer and industrial products is generally avoided.

67. The study continues with heating of various BPO-containing products at 34°C, 50°C and 80°C, finding substantial benzene formation at elevated temperatures, even exceeding levels found in Valisure’s March 2024 public citizens petition. Furthermore, similar to Valisure’s results, Rastogi finds that only formulations of BPO are unstable, while BPO alone is relatively stable:

Even heating of BPO-phthalate mixtures at 50°C produced significant amounts of benzene (approximately 0.3% [3,000 ppm]), while no benzene production was detected when benzoyl peroxide was heated alone at this temperature (Table 2).<sup>66</sup>

68. The referenced 1993 Rastogi article above, titled “Residues of Benzene in Chemical Products,” has also been flagged by the EPA as part of its Health & Environmental Research Online (“HERO”) system.<sup>67</sup>

69. Chemical evidence of carcinogenicity has been reported since at least 1981.<sup>68</sup> Multiple studies in the 1980s were conducted using animal models that suggested carcinogenic potential of benzoyl peroxide, including the use of commercial drug formulations of BPO like that

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<sup>65</sup> Rastogi, S.C. Residues of benzene in chemical products. Bull. Environ. Contam. Toxicol. 50, 794-797 (1993). <https://doi.org/10.1007/BF00209940>.

<sup>66</sup> *Id.*

<sup>67</sup> US Environmental Protection Agency. Health & Environmental Research Online (HERO). “Residues of Benzene in Chemical Products.” HERO ID 2894703 ([http://hero.epa.gov/hero/index.cfm/reference/details/reference\\_id/2894703](http://hero.epa.gov/hero/index.cfm/reference/details/reference_id/2894703)).

<sup>68</sup> Slaga TJ, Klein-Szanto AJ, Triplett LL, Yotti LP, Trosko KE. Skin tumor-promoting activity of benzoyl peroxide, a widely used free radical-generating compound. Science. 1981 Aug 28;213(4511):1023-5. doi: 10.1126/science.6791284. PMID: 6791284.

of PanOxyl Gel.<sup>69</sup>

70. In 1991, FDA posted an amendment to the monograph for OTC topical acne drug products because, “the agency became aware of a 1981 study by Slage, et al. ([FDA] Ref. 1) that raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice and a 1984 study by Kurokawa, et al. ([FDA] Ref. 2) that reported benzoyl peroxide to have tumor initiation potential,” leading FDA to determine that “further study is necessary to adequately assess the tumorigenic potential of benzoyl peroxide.”<sup>70</sup>

71. By 2010, FDA published a final monograph on benzoyl peroxide along with summarizing results from further studies on the potential carcinogenicity of benzoyl peroxide and actions of the FDA Advisory Committee. This final monograph stated, “The Committee recommended, by a four-to-three vote (with one abstention), that the known safety data regarding the tumor promoting potential of benzoyl peroxide should be communicated to consumers. Because this data was inconclusive, the Committee unanimously agreed that the word, “cancer” should not be included in the labeling of acne drug products containing benzoyl peroxide. The Committee was concerned that the word “cancer” would cause consumers to avoid using these products (even though the data were inconclusive).<sup>71</sup>

72. In 2020, the FDA started working with companies to identify benzene in products,

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<sup>69</sup> Kurokawa Y, Takamura N, Matsushima Y, Imazawa T, Hayashi Y. *Studies on the promoting and complete carcinogenic activities of some oxidizing chemicals in skin carcinogenesis*. Cancer Lett. 1984 Oct;24(3):299-304. doi: 10.1016/0304-3835(84)90026-0. PMID: 6437666; Pelling JC, Fischer SM, Neades R, Strawhecker J, Schweickert L. *Elevated expression and point mutation of the Ha-ras proto-oncogene in mouse skin tumors promoted by benzoyl peroxide and other promoting agents*. Carcinogenesis. 1987 Oct;8(10):1481-4. doi: 10.1093/carcin/8.10.1481. PMID: 3115617; 81 O'Connell JF, Klein-Szanto AJ, DiGiovanni DM, Fries JW, Slaga TJ. *Enhanced malignant progression of mouse skin tumors by the free-radical generator benzoyl peroxide*. Cancer Res. 1986 Jun;46(6):2863-5. PMID: 3084079; 82 Iversen OH. *Carcinogenesis studies with benzoyl peroxide (Panoxyl gel 5%)*. J Invest Dermatol. 1986 Apr;86(4):442-8. doi: 10.1111/1523-1747.ep12285787. PMID: 3091706.

<sup>70</sup> Food and Drug Administration. *Proposed Rule: Reclassifies benzoyl peroxide from GRASE to Category III*. (August 7, 1991) Federal Register, 56FR37622. pp 37622 - 37635 (<https://cdn.loc.gov/service/ll/fedreg/fr056/fr056152/fr056152.pdf#page=178>).

<sup>71</sup> Food and Drug Administration. Final Monograph. (March 4, 2010) Federal Register, 75FR9767. (<https://www.gpo.gov/fdsys/pkg/FR-2010-03-04/pdf/2010-4424.pdf>).

which resulted in product recalls of hand sanitizers, sunscreens, and deodorants. In 2021, an independent chemical analysis by Valisure of hundreds of sunscreens and after-sun care products from 69 brands found 27% of the batches had significant levels of benzene above 2 ppm.<sup>72</sup>

73. Thus, by 2021, Defendant was well aware of benzene contamination issues in its BPO Products and in products of their competitors.

74. Further, Defendant, which markets itself as a merchandiser of quality acne treatment products and employs high-level scientists, chemists, and researchers to formulate and/or decide which drug products to label and sell for public use, was aware of the well-known chemical processes that degrade its BPO Products into benzene when exposed to common used temperatures and conditions.

75. Defendant, as a large, sophisticated corporation in the business of manufacturing, distributing, and selling products containing BPO, knew or should have known the BPO Products were contaminated with excess levels of benzene and that testing the BPO Products for benzene was necessary to protect Plaintiffs and Class members from harmful levels of benzene exposure.

76. Defendant's use of BPO put it on notice of the excessive levels of benzene in the BPO Products.

77. Notwithstanding this knowledge, Defendant failed to appropriately and adequately test its BPO Products for the presence of benzene to protect Plaintiffs and Class members from dangerous levels of benzene exposure.

78. Defendant sold, and continues to sell, BPO Products during the class period despite its knowledge of the risk of benzene contamination.

79. Benzene is not listed on the BPO Products' labels as an ingredient, nor is there any warning about the inclusion (or even potential inclusion) of benzene in the BPO Products. The following image shows an example:

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<sup>72</sup> Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products, May 24, 2021.







80. Plaintiffs have standing to represent members of the putative Class because there is sufficient similarity between the specific BPO Product purchased by Plaintiffs and the other BPO

Products not purchased by Plaintiffs. Specifically, each and every one of the BPO Products (i) are marketed in substantially the same way – as an acne cleansing treatment— and (ii) fail to include labeling indicating to consumers that the BPO Products contain benzene or degrade into benzene. Accordingly, the misleading effect of all the BPO Products’ labels are substantially the same.

81. Defendant has engaged in deceptive, untrue, and misleading advertising by making representations by failing to warn about the presence of benzene in the BPO Products.

82. As alleged, the presence of benzene in the BPO Products renders the BPO Products misbranded and adulterated and therefore illegal and unfit for sale in trade or commerce. Plaintiffs would not have purchased the BPO Products had they been truthfully and accurately labeled.

83. Had Defendant adequately tested its BPO Products for benzene and other carcinogens and impurities, it would have discovered its BPO Products contained benzene – at levels above 2 ppm, making the BPO Products illegal to distribute, market, and sell.

84. Accordingly, Defendant knowingly, recklessly, or at least negligently, introduced the contaminated, adulterated, and misbranded BPO Products into the U.S. market.

85. Defendant’s concealment was material and intentional because people are concerned with what is contained in the products they are putting onto and into their bodies. Consumers such as Plaintiffs and Class members make purchasing decisions based on the representations made on the BPO Products’ labeling, including the ingredients listed.

## **VI. Injuries to Plaintiffs and Class Members**

86. When Plaintiffs purchased Defendant’s BPO Products, Plaintiffs did not know, and had no reason to know, that Defendant’s BPO Products contained or would degrade into the harmful carcinogen benzene. Not only would Plaintiffs not have purchased Defendants’ BPO Products had she known the Products contained or would degrade into benzene, but they would also not have been capable of purchasing them if Defendant had done as the law required and tested the BPO Products for benzene and other carcinogens and impurities.

87. Consumers lack the ability to test or independently ascertain or verify whether a

product contains unsafe substances, such as benzene, especially at the point of sale, and therefore must rely on Defendant to truthfully and honestly report on the BPO Product's packaging and labeling what the Products contain.

88. Further, given Defendant's position as a leader in the acne treatment market, Plaintiffs and reasonable consumers trusted and relied on Defendant's representations and omissions regarding the presence of benzene in the BPO Products.

89. Defendant's false, misleading, omissions, and deceptive misrepresentations regarding the presence of benzene in the BPO Products are likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiffs and the Class members.

90. Plaintiffs and Class members bargained for products free of contaminants and dangerous substances. Plaintiffs and Class members were injured by the full purchase price of the BPO Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene and Defendants failed to warn consumers of this fact. Such illegally sold products are worthless and have no value.

91. As a proximate result thereof, Plaintiffs and Class members are entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

92. All conditions precedent to the prosecution of this action have occurred, and/or have been performed, excused, or otherwise waived.

### **CLASS ALLEGATIONS**

93. Plaintiffs, individually and on behalf of all others similarly situated, bring this class action pursuant to Fed. R. Civ. P. 23.

94. Plaintiffs seeks to represent classes defined as:

#### **Missouri Class**

All persons who purchased the BPO Products in the State of Missouri for personal or household use within the applicable limitations period.

**Louisiana Class**

All persons who purchased the BPO Products in the State of Louisiana for personal or household use within the applicable limitations period.

95. Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendant, Defendant's subsidiaries, parents, successors, predecessors, and any entities in which Defendant or its parents and any entities in which Defendant has a controlling interest and its current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of the BPO Products.

96. Plaintiffs reserve the right to modify, change, or expand the definitions of the Class based upon discovery and further investigation.

97. *Numerosity*: The Class is so numerous that joinder of all members is impracticable. The Class likely contains hundreds of thousands of members based on publicly available data. The Class is ascertainable by records in Defendant's possession.

98. *Commonality*: Questions of law or fact common to the Class include:

- a. Whether the BPO Products contain benzene;
- b. Whether a reasonable consumer would consider the presence of benzene in the BPO Products to be material;
- c. Whether Defendant knew or should have known that the BPO Products contains benzene;
- d. Whether Defendant misrepresented the BPO Products contain or degrade into benzene;

- e. Whether Defendant failed to disclose that the BPO Products contain or degrade into benzene;
- f. Whether Defendant concealed that the BPO Products contain or degrade into benzene;
- g. Whether Defendant engaged in unfair or deceptive trade practices;
- h. Whether Defendant violated the state consumer protection statutes alleged herein;
- i. Whether Defendant was unjustly enriched; and
- j. Whether Plaintiffs and Class members are entitled to damages.

99. *Typicality*: Plaintiffs' claims are typical of the claims of Class members. Plaintiffs and Class members were injured and suffered damages in substantially the same manner, have the same claims against Defendant relating to the same course of conduct, and are entitled to relief under the same legal theories.

100. *Adequacy*: Plaintiffs will fairly and adequately protect the interests of the Class and has no interests antagonistic to those of the Class. Plaintiffs have retained counsel experienced in the prosecution of complex class actions, including actions with issues, claims, and defenses similar to the present case. Counsel intends to vigorously prosecute this action.

101. *Predominance and superiority*: Questions of law or fact common to Class members predominate over any questions affecting individual members. A class action is superior to other available methods for the fair and efficient adjudication of this case because individual joinder of all Class members is impracticable and the amount at issue for each Class member would not justify the cost of litigating individual claims. Should individual Class members be required to bring separate actions, this Court would be confronted with a multiplicity of lawsuits burdening the court system while also creating the risk of inconsistent rulings and contradictory judgments.

In contrast to proceeding on a case-by-case basis, in which inconsistent results will magnify the delay and expense to all parties and the court system, this class action presents far fewer management difficulties while providing unitary adjudication, economies of scale and comprehensive supervision by a single court. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

102. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P. 23(b)(3).

**COUNT I – Violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.***

**(On Behalf of Plaintiff Flores and the Missouri Class)**

101. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

102. Plaintiff brings this Count I on behalf of the Missouri Class against Defendant.

103. The acts and practices engaged in by Defendant, and described herein, constitute unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*

104. Defendant engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution or advertisement of the BPO Products, in violation of Mo. Rev. Stat. § 407.020.

105. Plaintiff and the Class members purchased the BPO Products, Products that were falsely represented, as stated above, in violation of the Missouri Merchandising Practices Act, and as a result, Plaintiff and the Class members suffered economic damages in that the BPO Products

were worth less than the product they thought they had purchased had Defendant's representations been true.

## **COUNT II – Redhibition**

### **(On Behalf of Plaintiff Grossenbacher and the Louisiana Class)**

126. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

127. Plaintiff brings this Count II individually and on behalf of the Louisiana Class members against Defendant.

128. Plaintiff and Class members are “buyers” and Defendant is a “manufacturer” of the BPO Products under La. C.C. Art. 2520, *et seq.*

129. Under Louisiana law, the manufacturer warrants the buyer against redhibitory defects or vices in the things sold. La. C.C.P. Art. 2520.

130. Under Louisiana Civil Code Article 2520, a defect is redhibitory in two situations: (1) When the defect “renders the thing useless, or its use so inconvenient” that it has to be presumed that the buyer would not have bought the thing had he known of the defect or (2) when, “without rendering the thing totally useless,” the defect diminishes the product's usefulness or its value such that it must be presumed that the buyer would still have bought it but for a lesser price.

131. Defendant's BPO Products contain a vice or defect which renders them useless and ineffective, as they contain excessive levels of benzene which render the Products dangerous to human health and illegal to sell.

132. Had Plaintiff and Class members known that the BPO Products contained benzene, they would not have purchased the Products at all, or at least not for the price paid, and thus the defects in the Products as described above, meet the definition of a redhibitory defect.

133. Under a redhibition claim the inquiry is not subjective but objective and looks “into the deficiency and whether it diminishes the product’s value or renders it so inconvenient that the reasonable buyer would not have purchased it had he known of the deficiency.” *Mire v. Eatelcorp., Inc.*, 927 So. 2d 1113, 1120 (La. Ct. App. 2005), *writ denied*, 926 So. 2d 549 (La. 2006).

134. At the time of the sale of Defendant’s BPO Products to Plaintiff and Class members, Defendant had actual or constructive notice of benzene contamination based on prior regulatory and scientific action and investigation.

135. As a manufacturer, Defendant is deemed to have knowledge of any redhibitory defect in any product it sells. La. C.C.P. Art. 2545.

136. When bringing a redhibition claim under Louisiana law, plaintiffs are entitled to damages including “reasonable attorney fees.” La. Civ. Code art. 2545.

137. Wherefore, Plaintiff and members of the Louisiana Class are entitled to injunctive relief, compensatory damages, equitable and declaratory relief, costs and reasonable attorneys’ fees.

### **COUNT III – Fraud (Fraudulent Misrepresentation)**

#### **(On Behalf of all Plaintiffs against Defendant)**

106. Plaintiffs incorporate by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

107. Plaintiffs bring this Count III on behalf of the Missouri and Louisiana Classes against Defendant.

108. Defendant intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality or grade of the BPO Products.

109. Due to Defendant’s fraudulent conduct, Plaintiffs and the other Class members



have suffered actual damages.

110. Defendant knew or should have known that the BPO Products contain benzene or degrade into benzene when used as directed.

111. Defendant knew or should have known that its concealment and suppression of material facts was false and misleading and knew the effect of concealing those material facts.

112. Defendant acted with malice, oppression, and fraud.

113. Defendants knew or should have known of the dangers associated with benzene in its BPO Products based on regulatory studies and regulatory guidance.

114. Defendant was obligated to inform Plaintiffs and the other Class members of the dangers associated with benzene in the BPO Products due to their exclusive and superior knowledge of the Products.

115. Plaintiffs and other Class members also expressly reposed a trust and confidence in Defendant because of their dealings as a healthcare entity and with Plaintiffs and other Class members as their customers.

116. Plaintiffs and the other Class members would not have purchased the BPO Products but for Defendant's omissions and concealment of material facts regarding the nature and quality of the Products, or would have paid less for the Products.

117. Plaintiffs and Class members were justified in relying on Defendant's misrepresentations and/or omissions.

118. As alleged herein, Plaintiffs and the Class members have suffered injury in fact and lost money as a result of Defendant's conduct because they purchased BPO Products from Defendant in reliance on Defendant's misrepresentation and/or omissions that the BPO Products were safe to use as directed.

119. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the BPO Products.

**COUNT IV – Negligent Misrepresentation**  
**(On Behalf of all Plaintiffs against Defendant)**

120. Plaintiffs incorporate by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

121. Plaintiffs bring this Count IV on behalf of the Missouri and Louisiana Classes against Defendant.

122. Defendant owed a duty of reasonable care to Plaintiffs and the Class members in the labeling, manufacturing, sale, and distribution of its BPO Products.

123. Defendant also had a duty to exercise reasonable care in properly and accurately representing the safety of its BPO Products to consumers, including Plaintiffs and the Class members.

124. Defendant failed to exercise ordinary care when making the misrepresentations and/or omissions in their marketing and labeling, claiming that their BPO Products were safe.

125. Defendant negligently and falsely misrepresented facts regarding the safety of its BPO products to Plaintiffs and the Class members.

126. Defendant knew or should have known that the misrepresentations regarding the safety of its BPO Products was misleading. Defendant knew or should have known that these misrepresentations would induce Plaintiffs and the Class members to purchase the BPO Products in reliance of Defendant's claims.

127. As a direct and proximate cause of Defendant's negligent misrepresentations,

Plaintiffs and the Class members have suffered harm.

128. Defendant's misrepresentations were material and substantial factors in Plaintiffs and Class members purchasing and paying for the BPO Products.

129. Defendant intended, or had reckless disregard, to induce Plaintiffs and Class members to purchase its BPO Products based on its misrepresentations of safety. Plaintiffs and Class members reasonably relied on the misrepresentations made by Defendant.

130. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the BPO Products.

#### **COUNT V – Unjust Enrichment**

##### **(On Behalf of all Plaintiffs against Defendant)**

131. Plaintiffs incorporate by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

132. Plaintiffs bring this Count V on behalf of the Missouri and Louisiana Classes against Defendant.

133. Defendant profited exponentially from its marketing and sales of its benzene-contaminated BPO Products. Plaintiffs and Class members were deprived of the money paid for these defective and unsafe products.

134. Defendant was unjustly enriched by unlawfully receiving money from Plaintiffs for defective and unsafe products. It would be inequitable and unconscionable for Defendant to retain the compensation obtained based on its wrongful conduct.

135. Wherefore, as a direct and proximate result thereof, Plaintiffs and members of the Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on

the BPO Products as well as an order from this Court requiring the disgorgement of all profits, benefits, and additional compensation obtained by Defendant by way of its wrongful conduct.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment against the Defendant as to each and every count, including:

- A. An order declaring this action to be a proper class action, appointing Plaintiffs and their counsel to represent the Class, and requiring Defendant to bear the costs of class notice;
- B. An order enjoining Defendant from selling the BPO Products;
- C. An order enjoining Defendant from suggesting or implying that they are safe for human application;
- D. An order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling existing BPO Products;
- E. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's past conduct;
- F. An order requiring Defendant to pay restitution/damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising in violation of the above-cited authority, plus pre- and post-judgment interest thereon;

- G. An order requiring Defendant to disgorge any ill-gotten benefits received from Plaintiffs and members of the Class as a result of any wrongful or unlawful act or practice;
- H. An order requiring Defendant to pay all actual and statutory damages permitted under the counts alleged herein;
- I. An order awarding attorneys' fees and costs to Plaintiffs and the Class; and
- J. An order providing for all other such equitable relief as may be just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs demand a trial by jury on all issues so triable.

DATED: March 25, 2024

/s/ Thomas P. Cartmell  
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